# House File 2384 - Reprinted

HOUSE FILE 2384
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 623)

(As Amended and Passed by the House March 23, 2022)

## A BILL FOR

- 1 An Act relating to pharmacy benefits managers, pharmacies, and
- 2 prescription drug benefits, and including applicability
- 3 provisions.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

- 1 Section 1. Section 505.26, subsection 1, paragraph b, Code
- 2 2022, is amended to read as follows:
- 3 b. "Pharmacy benefits manager" means the same as defined in
- 4 section 510B.1 510C.1.
- 5 Sec. 2. Section 507B.4, subsection 3, Code 2022, is amended
- 6 by adding the following new paragraph:
- 7 NEW PARAGRAPH. t. Pharmacy benefits managers. Any
- 8 violation of chapter 510B by a pharmacy benefits manager.
- 9 Sec. 3. Section 510B.1, Code 2022, is amended by striking
- 10 the section and inserting in lieu thereof the following:
- 11 510B.1 Definitions.
- 12 As used in this chapter, unless the context otherwise
- 13 requires:
- 14 1. "Clean claim" means a claim that has no defect or
- 15 impropriety, including a lack of any required substantiating
- 16 documentation, or other circumstances requiring special
- 17 treatment, that prevents timely payment from being made on the
- 18 claim.
- 19 2. "Commissioner" means the commissioner of insurance.
- "Cost-sharing" means any coverage limit, copayment,
- 21 coinsurance, deductible, or other out-of-pocket cost obligation
- 22 imposed by a health benefit plan on a covered person.
- 23 4. "Covered person" means a policyholder, subscriber, or
- 24 other person participating in a health benefit plan that has
- 25 a prescription drug benefit managed by a pharmacy benefits
- 26 manager.
- 27 5. "Health benefit plan" means the same as defined in
- 28 section 514J.102.
- 29 6. "Health care professional" means the same as defined in
- 30 section 514J.102.
- 31 7. "Health carrier" means an entity subject to the
- 32 insurance laws and regulations of this state, or subject
- 33 to the jurisdiction of the commissioner, including an
- 34 insurance company offering sickness and accident plans, a
- 35 health maintenance organization, a nonprofit health service

- 1 corporation, a plan established pursuant to chapter 509A
- 2 for public employees, or any other entity providing a plan
- 3 of health insurance, health care benefits, or health care
- 4 services. "Health carrier" does not include the department
- 5 of human services, or a managed care organization acting
- 6 pursuant to a contract with the department of human services to
- 7 administer the medical assistance program under chapter 249A
- 8 or the healthy and well kids in Iowa (hawk-i) program under
- 9 chapter 514I.
- 10 8. "Maximum allowable cost" means the maximum amount that a
- 11 pharmacy will be reimbursed by a pharmacy benefits manager or a
- 12 health carrier for a generic drug, brand-name drug, biologic
- 13 product, or other prescription drug, and that may include any
- 14 of the following:
- 15 a. Average acquisition cost.
- 16 b. National average acquisition cost.
- 17 c. Average manufacturer price.
- 18 d. Average wholesale price.
- 19 e. Brand effective rate.
- 20 f. Generic effective rate.
- 21 q. Discount indexing.
- 22 h. Federal upper limits.
- 23 i. Wholesale acquisition cost.
- j. Any other term used by a pharmacy benefits manager or a
- 25 health carrier to establish reimbursement rates for a pharmacy.
- 9. "Maximum allowable cost list" means a list of
- 27 prescription drugs that includes the maximum allowable cost
- 28 for each prescription drug and that is used, directly or
- 29 indirectly, by a pharmacy benefits manager.
- 30 10. "Pharmacist" means the same as defined in section
- 31 155A.3.
- 32 11. "Pharmacy" means the same as defined in section 155A.3.
- 33 12. "Pharmacy acquisition cost" means the cost to a
- 34 pharmacy for a prescription drug as invoiced by a wholesale
- 35 distributor, and reduced by any discounts, rebates, or other

- 1 price concessions applicable to the prescription drug that are
- 2 not shown on the invoice and are known at the time that the
- 3 pharmacy files an appeal with a pharmacy benefits manager.
- 4 13. "Pharmacy benefits manager" means the same as defined
- 5 in section 510C.1.
- 6 14. "Pharmacy benefits manager affiliate" means a pharmacy or
- 7 a pharmacist that directly or indirectly through one or more
- 8 intermediaries, owns or controls, is owned and controlled by,
- 9 or is under common ownership or control of, a pharmacy benefits 10 manager.
- 11 15. "Pharmacy network" or "network" means pharmacies that
- 12 have contracted with a pharmacy benefits manager to dispense
- 13 or sell prescription drugs to covered persons of a health
- 14 benefit plan for which the pharmacy benefits manager manages
- 15 the prescription drug benefit.
- 16. "Prescription drug" means the same as defined in section
- 17 155A.3.
- 18 17. "Prescription drug benefit" means the same as defined
- 19 in section 510C.1.
- 20 18. "Prescription drug order" means the same as defined in
- 21 section 155A.3.
- 22 19. "Rebate" means the same as defined in section 510C.1.
- 23 20. "Wholesale distributor" means the same as defined in
- 24 section 155A.3.
- 25 Sec. 4. Section 510B.4, Code 2022, is amended to read as
- 26 follows:
- 27 510B.4 Performance of duties good faith conflict of
- 28 interest.
- 29 1. A pharmacy benefits manager shall perform the pharmacy
- 30 benefits manager's duties exercising exercise good faith and
- 31 fair dealing in the performance of its the pharmacy benefits
- 32 manager's contractual obligations toward the covered entity a
- 33 health carrier.
- 34 2. A pharmacy benefits manager shall notify the covered
- 35 entity a health carrier in writing of any activity, policy,

- 1 practice ownership interest, or affiliation of the pharmacy
- 2 benefits manager that presents any conflict of interest.
- 3. A pharmacy benefits manager shall act in the best
- 4 interest of each health carrier for whom the pharmacy benefits
- 5 manager manages a prescription drug benefit provided by the
- 6 health carrier, and shall discharge its duties in accordance
- 7 with applicable state and federal law.
- 8 4. A pharmacy benefits manager, health carrier, or health
- 9 benefit plan shall not discriminate against a pharmacy
- 10 or a pharmacist with respect to participation, referral,
- 11 reimbursement of a covered service, or indemnification if a
- 12 pharmacist is acting within the scope of the pharmacist's
- 13 license.
- 14 Sec. 5. Section 510B.5, Code 2022, is amended to read as
- 15 follows:
- 16 510B.5 Contacting covered individual persons requirements.
- 17 A pharmacy benefits manager, unless authorized pursuant to
- 18 the terms of its contract with a covered entity health carrier,
- 19 shall not contact any covered individual person without
- 20 the express written permission of the covered entity health
- 21 carrier.
- Sec. 6. Section 510B.6, Code 2022, is amended to read as
- 23 follows:
- 24 510B.6 Dispensing of substitute Substitute prescription drug
- 25 for prescribed drug drugs.
- 26 1. The following provisions shall apply when if a pharmacy
- 27 benefits manager requests the dispensing of a substitute
- 28 prescription drug for a prescribed drug to prescribed for a
- 29 covered individual person:
- 30 a. The pharmacy benefits manager may request the
- 31 substitution of a lower priced generic and therapeutically
- 32 equivalent prescription drug for a higher priced prescribed
- 33 prescription drug.
- 34 b. If the substitute prescription drug's net cost to the
- 35 covered individual person or covered entity to the health

- 1 carrier exceeds the cost of the prescribed prescription drug
- 2 originally prescribed for the covered person, the substitution
- 3 shall be made only for medical reasons that benefit the covered
- 4 individual person.
- 5 2. A pharmacy benefits manager shall obtain the approval of
- 6 the prescribing practitioner health care professional prior to
- 7 requesting any substitution under this section.
- 8 3. A pharmacy benefits manager shall not substitute an
- 9 equivalent prescription drug contrary to a prescription drug
- 10 order that prohibits a substitution.
- 11 Sec. 7. Section 510B.7, Code 2022, is amended by striking
- 12 the section and inserting in lieu thereof the following:
- 13 510B.7 Pharmacy networks.
- 14 l. A pharmacy located in the state shall not be prohibited
- 15 from participating in a pharmacy network provided that the
- 16 pharmacy accepts the same terms and conditions as the pharmacy
- 17 benefits manager imposes on the pharmacies in the network.
- 18 2. A pharmacy benefits manager shall not assess, charge, or
- 19 collect any form of remuneration that passes from a pharmacy
- 20 or a pharmacist in a pharmacy network to the pharmacy benefits
- 21 manager including but not limited to claim processing fees,
- 22 performance-based fees, network participation fees, or
- 23 accreditation fees.
- Sec. 8. Section 510B.8, Code 2022, is amended by striking
- 25 the section and inserting in lieu thereof the following:
- 26 510B.8 Prescription drugs point of sale.
- 27 l. A covered person shall not be required to make a
- 28 cost-sharing payment at the point of sale for a prescription
- 29 drug in an amount that exceeds the total amount that the
- 30 pharmacy at which the covered person fills the covered person's
- 31 prescription drug order is reimbursed.
- 32 2. A pharmacy benefits manager shall not prohibit a pharmacy
- 33 from disclosing the availability of a lower-cost prescription
- 34 drug option to a covered person, or from selling a lower-cost
- 35 prescription drug option to a covered person.

- 1 3. Any amount paid by a covered person for a prescription
- 2 drug purchased pursuant to this section shall be applied to any
- 3 deductible imposed by the covered person's health benefit plan 4 in accordance with the health benefit plan coverage documents.
- 5 4. A covered person shall not be prohibited from filling
- 6 a prescription drug order at any pharmacy located in the
- 7 state provided that the pharmacy accepts the same terms and
- 8 conditions as the pharmacies participating in the covered
- 9 person's health benefit plan's network.
- 10 5. Excluding incentives in value-based programs established
- 11 by a health carrier or a pharmacy benefits manager to promote
- 12 the use of higher quality pharmacies, a pharmacy benefits
- 13 manager shall not impose different cost-sharing or additional
- 14 fees on a covered person based on the pharmacy at which the
- 15 covered person fills the covered person's prescription drug
- 16 order.
- 17 6. A pharmacy benefits manager shall not require a covered
- 18 person, as a condition of payment or reimbursement, to purchase
- 19 pharmacy services, including prescription drugs, exclusively
- 20 through a mail-order pharmacy.
- 21 7. a. For purposes of calculating a covered person's
- 22 contribution toward the covered person's cost-sharing, a
- 23 pharmacy benefits manager shall include all cost-sharing paid
- 24 by the covered person and all cost-sharing paid by any other
- 25 person on behalf of the covered person.
- 26 b. If application of paragraph "a" will result in health
- 27 savings account ineligibility under section 223 of the Internal
- 28 Revenue Code, paragraph "a" shall only apply to the covered
- 29 person's deductible for a health savings account qualified-high
- 30 deductible health plan after the covered person has satisfied
- 31 the minimum deductible under section 223 of the Internal
- 32 Revenue Code, except for items or services that are preventive
- 33 care, in which case, the requirement shall apply regardless of
- 34 if the minimum deductible under section 223 of the Internal
- 35 Revenue Code has been satisfied. For purposes of this section,

- 1 "preventive care" means the same as under section 223(c)(2)(C)
- 2 of the Internal Revenue Code.
- 3 c. Paragraph "a" shall not apply to cost-sharing paid by
- 4 a covered person, or to cost-sharing paid by any other person
- 5 on behalf of the covered person, for a specialty drug or for
- 6 a prescription drug for which a medically appropriate A-rated
- 7 generic equivalent or an interchangeable biological product is
- 8 available to the covered person.
- 9 d. Paragraph "a" shall not apply to a state-regulated
- 10 high-deductible health plan to the extent application
- ll of paragraph "a" will result in the state-regulated
- 12 high-deductible health plan not qualifying as a high-deductible
- 13 health plan under section 223 of the Internal Revenue Code.
- 14 e. If paragraph "a" conflicts with a federal law or a
- 15 federal regulation as applied to a specific health carrier or
- 16 to a specific circumstance, paragraph "a" shall apply to all
- 17 health carriers and in all circumstances in which the federal
- 18 law or federal regulation does not conflict.
- 19 Sec. 9. NEW SECTION. 510B.8A Maximum allowable cost lists.
- 20 l. Prior to placement of a particular prescription drug on a
- 21 maximum allowable cost list, a pharmacy benefits manager shall
- 22 ensure that all of the following requirements are met:
- 23 a. The particular prescription drug must be listed as
- 24 therapeutically and pharmaceutically equivalent in the most
- 25 recent edition of the publication entitled "Approved Drug
- 26 Products with Therapeutic Equivalence Evaluations", published
- 27 by the United States food and drug administration, otherwise
- 28 known as the orange book.
- 29 b. The particular prescription drug must not be obsolete or
- 30 temporarily unavailable.
- 31 c. The particular prescription drug must be available for
- 32 purchase, without limitations, by all pharmacies in the state
- 33 from a national or regional wholesale distributor that is
- 34 licensed in the state.
- 35 2. For each maximum allowable cost list that a pharmacy

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- 1 benefits manager uses in the state, the pharmacy benefits
- 2 manager shall do all of the following:
- a. Provide each pharmacy in a pharmacy network reasonable
- 4 access to the maximum allowable cost list to which the pharmacy
- 5 is subject.
- 6 b. Update the maximum allowable cost list within seven
- 7 calendar days from the date of an increase of ten percent or
- 8 more in the pharmacy acquisition cost of a prescription drug on
- 9 the list by one or more wholesale distributors doing business
- 10 in the state.
- 11 c. Update the maximum allowable cost list within seven
- 12 calendar days from the date of a change in the methodology, or
- 13 a change in the value of a variable applied in the methodology,
- 14 on which the maximum allowable cost list is based.
- 15 d. Provide a reasonable process for each pharmacy in a
- 16 pharmacy network to receive prompt notice of all changes to the
- 17 maximum allowable cost list to which the pharmacy is subject.
- 18 Sec. 10. NEW SECTION. 510B.8C Pharmacy benefits manager
- 19 affiliates reimbursement.
- 20 A pharmacy benefits manager shall not reimburse any pharmacy
- 21 located in the state in an amount less than the amount that
- 22 the pharmacy benefits manager reimburses a pharmacy benefits
- 23 manager affiliate for dispensing the same prescription drug
- 24 as dispensed by the pharmacy. The reimbursement amount shall
- 25 be calculated on a per unit basis based on the same generic
- 26 product identifier or generic code number.
- 27 Sec. 11. NEW SECTION. 510B.8D Clean claims.
- 28 After the date of receipt of a clean claim submitted by a
- 29 pharmacy in a pharmacy network, a pharmacy benefits manager
- 30 shall not retroactively reduce payment on the claim, either
- 31 directly or indirectly except in the following circumstances:
- 32 a. The claim is found not to be a clean claim during the
- 33 course of a routine audit.
- 34 b. The claim submission was fraudulent.
- 35 c. The claim submission was a duplicate submission of a

- 1 claim for which the pharmacy had already received payment.
- 2 Sec. 12. NEW SECTION. 510B.8E Appeals and disputes.
- A pharmacy benefits manager shall provide a reasonable
- 4 process to allow a pharmacy to appeal a maximum allowable cost
- 5 or reimbursement rate for a specific prescription drug for any
- 6 of the following reasons:
- 7 a. The pharmacy benefits manager violated section 510B.8A.
- 8 b. The maximum allowable cost or the reimbursement rate is
- 9 below the pharmacy acquisition cost.
- 10 2. The appeal process must include all of the following:
- 11 a. A dedicated telephone number at which a pharmacy may
- 12 contact the pharmacy benefits manager and speak directly with
- 13 an individual involved in the appeal process.
- 14 b. A dedicated electronic mail address or internet site for
- 15 the purpose of submitting an appeal directly to the pharmacy
- 16 benefits manager.
- 17 c. A period of at least thirty business days after the date
- 18 of a pharmacy's initial submission of a clean claim during
- 19 which the pharmacy may initiate an appeal.
- 20 3. A pharmacy benefits manager shall respond to an appeal
- 21 within seven business days after the date on which the pharmacy
- 22 benefits manager receives the appeal.
- 23 a. If the pharmacy benefits manager grants a pharmacy's
- 24 appeal, the pharmacy benefits manager shall do all of the
- 25 following:
- 26 (1) Adjust the maximum allowable cost or the reimbursement
- 27 rate of the prescription drug that is the subject of the appeal
- 28 and provide the national drug code number that the adjustment
- 29 is based on to the appealing pharmacy.
- 30 (2) Permit the appealing pharmacy to reverse and resubmit
- 31 the claim that is the subject of the appeal.
- 32 (3) Make the adjustment pursuant to subparagraph (1)
- 33 applicable to all of the following:
- 34 (a) Each pharmacy that is under common ownership with the
- 35 pharmacy that submitted the appeal.

- 1 (b) Each pharmacy in the state that demonstrates the
- 2 inability to purchase the prescription drug for less than the
- 3 established maximum allowable cost or reimbursement rate.
- 4 b. If the pharmacy benefits manager denies a pharmacy's
- 5 appeal, the pharmacy benefits manager shall do all of the
- 6 following:
- 7 (1) Provide the appealing pharmacy the national drug
- 8 code number and the name of a wholesale distributor licensed
- 9 pursuant to section 155A.17 from which the pharmacy can obtain
- 10 the prescription drug at or below the maximum allowable cost
- ll or reimbursement rate.
- 12 (2) If the prescription drug identified by the national drug
- 13 code number provided by the pharmacy benefits manager pursuant
- 14 to subparagraph (1) is not available below the pharmacy
- 15 acquisition cost from the wholesale distributor from whom the
- 16 pharmacy purchases the majority of its prescription drugs for
- 17 resale, the pharmacy benefits manager shall adjust the maximum
- 18 allowable cost or the reimbursement rate above the appealing
- 19 pharmacy's pharmacy acquisition cost, and permit the pharmacy
- 20 to reverse and resubmit each claim affected by the pharmacy's
- 21 inability to procure the prescription drug at a cost that is
- 22 equal to or less than the previously appealed maximum allowable
- 23 cost or the reimbursement rate.
- Sec. 13. Section 510B.9, Code 2022, is amended to read as
- 25 follows:
- 26 510B.9 Submission, approval, and use of prior Prior
- 27 authorization form.
- 28 A pharmacy benefits manager shall file with and have
- 29 approved by the commissioner a single prior authorization
- 30 form as provided in section 505.26 comply with all applicable
- 31 prior authorization requirements pursuant to section 505.26.
- 32 A pharmacy benefits manager shall use the single prior
- 33 authorization form as provided in section 505.26.
- 34 Sec. 14. Section 510B.10, Code 2022, is amended by striking
- 35 the section and inserting in lieu thereof the following:

- 1 510B.10 Enforcement.
- The commissioner may take any enforcement action under
- 3 the commissioner's authority to enforce compliance with this
- 4 chapter.
- 5 2. After notice and hearing, the commissioner may issue any
- 6 order or impose any penalty pursuant to section 507B.7, and may
- 7 suspend or revoke a pharmacy benefits manager's certificate
- 8 of registration as a third-party administrator upon a finding
- 9 that the pharmacy benefits manager violated this chapter,
- 10 or any applicable requirements pertaining to third-party
- 11 administrators under chapter 510.
- 12 3. A pharmacy benefits manager shall be subject to the
- 13 commissioner's authority to conduct an examination pursuant to
- 14 chapter 507.
- 4. A pharmacy benefits manager is subject to the
- 16 commissioner's authority to conduct a proceeding pursuant
- 17 to chapter 507B. The procedures set forth in chapter 507B
- 18 regarding proceedings shall apply to a proceeding related to a
- 19 pharmacy benefits manager under this chapter.
- 20 5. A pharmacy benefits manager is subject to the
- 21 commissioner's authority to conduct an examination, audit,
- 22 or inspection pursuant to chapter 510 for third-party
- 23 administrators. The procedures set forth in chapter 510 for
- 24 third-party administrators shall apply to an examination,
- 25 audit, or inspection of a pharmacy benefits manager under this
- 26 chapter.
- 27 6. If the commissioner conducts an examination of a pharmacy
- 28 benefits manager under chapter 507; a proceeding under chapter
- 29 507B; or an examination, audit, or inspection under chapter
- 30 510, all information received from the pharmacy benefits
- 31 manager, and all notes, work papers, or other documents related
- 32 to the examination, proceeding, audit, or inspection shall
- 33 be confidential records pursuant to chapter 22 and shall be
- 34 accorded the same confidentiality as notes, work papers,
- 35 investigatory materials, or other documents related to the

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- 1 examination of an insurer as provided in section 507.14.
- 7. A violation of this chapter shall be an unfair or
- 3 deceptive act or practice in the business of insurance pursuant
- 4 to section 507B.4, subsection 3.
- 5 Sec. 15. NEW SECTION. 510B.11 Rules.
- 6 The commissioner may adopt rules pursuant to chapter 17A to
- 7 administer this chapter.
- 8 Sec. 16. NEW SECTION. 510B.12 Severability.
- 9 If a provision of this chapter or its application to any
- 10 person or circumstance is held invalid, the invalidity does
- 11 not affect other provisions or applications of this chapter
- 12 which can be given effect without the invalid provision or
- 13 application, and to this end the provisions of this chapter are
- 14 severable.
- 15 Sec. 17. REPEAL. Section 510B.3, Code 2022, is repealed.
- 16 Sec. 18. APPLICABILITY. 1. This Act applies to pharmacy
- 17 benefits managers that manage a health carrier's prescription
- 18 drug benefit in the state on or after the effective date of
- 19 this Act.
- 20 2. The following applies to all health benefit plans
- 21 delivered, issued for delivery, continued, or renewed in this
- 22 state on or after January 1, 2023:
- The section of this Act amending section 510B.8, subsection 24 7.